Patient-centered design, validation and fabrication of single-use medical devices, within 24 hours

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# Primary Objective:

Development and implementation of a methodology or process for the design, validation and fabrication of patient-specific, single-use medical devices, within 24 hours. The first case will be pediatric Intubation Laryngoscope.

# Description:

Given a clinical case in which standard medical equipment does not suit the anatomy and/or physiology of the patient, device customization can reduce injuries, complications, time and costs. Patient-specific device development requires advanced DICOM segmentation programs, engineering simulation tools, and additive manufacturing equipment.

# Methodology:

The process for the design, validation and fabrication of patient-specific, single use medical devices (Figure 1), comprises;

1. the acquisition of patient anatomical data,
2. the segmentation and 3D modeling of patient data,
3. the visualization of patient data for the collaborative design of a patient-specific device,
4. the simulation of the initial device design and its variations,
5. the validation of the resulting device design (and its variations or iterations), and
6. the fabrication of the resulting, validated device design

Each step of the overall process must be developed and refined prior to its complete, sequential implementation. Specific objectives for each step are as follows;

1. Patient data acquisition
   1. Selection of the most suitable imaging methodology for a given clinical case, anatomy or tissue type(s) (i.e.: MRI vs. CT)
   2. Determination of the appropriate imaging parameters for the purpose of enhancing segmentation and 3D modeling (i.e.: MRI protocol parameters)
2. Segmentation and 3D modeling of patient data
   1. Selection of suitable segmentation platform or software package – Assessment of license-based and open-source software packages (i.e.: Materialise Mimics vs. 3D Slicer)
   2. Segmentation automation as means for time and cost reduction
3. Patient data visualization for collaborative device design
   1. Implement University of Minnesota’s 3D Visualization Table for the projection and manipulation of patient data
   2. …
4. Validation of device design

# Available Technologies and Resources:

The process will make use of commercially-available technologies, open-source software, and tools developed previously by the University of Minnesota and the University of Central Florida. Some of these technologies encompass;

1. Segmentation programs such as 3D Slicer or Seg3D [Ref.]
2. 3D Visualization Table [Ref.]
3. Engineering simulation software packages including; ANSYS, Simulia, and FEBio [ref.]
4. Simulation data visualization using Design by Dragging [ref.]
5. Device fabrication using Stratasys XXX 3D printer

# Clinical Case:

The first application will be design and printing of a disposable laryngoscope device that will be directed towards the Pediatric Intubation procedure. This case is specifically critical and hard. The anatomy is small and the patient is fragile. The intubation blade design is traditionally fairly simple. Making it patient specific to the pediatric case will simplify the case and reduce trauma. Achieving the primary objective of the project would require

# Process and Milestones

In order to accomplish the primary goal of this proposal, the following objectives must be completed in sequence

## Consolidation and Re-deployment of Design by Dragging

Developed to direct design through the visualization of FEA data, the *Design by Dragging* platform has yet to be consolidated into a deployable software. In order to

# Potential funding sources and strategy

As of April 9 2018, both the University of Minnesota and the University of Central Florida have agreed to seek funding in parallel, covering local health centers and industries

## Elizabeth Morse Genius Foundation (Orlando, FL)

* The Morse Genius Foundation has awarded large grants to the University of Central Florida and, most specifically, to their Nursing Program
* The Morse Genius Foundation receives and reviews grants in March and September of every year
* The Morse Genius Foundation funds projects that seek to “improve the quality of life”